510(k) Notification K122380

GENERAL INFORMATION

NOV 7 2012

Applicant:

Avinger, Inc.
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Redwood City, CA 94063
U.S.A.
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Contact Person:

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Avinger, Inc.
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Date Prepared:

August 3, 2012

DEVICE INFORMATION

Trade Name:

Ocelot System

Generic/Common Name:

Percutaneous catheter

Classification:

21 CFR§870.1250, Percutaneous catheter, Class II

Product Code:

DQY,

PREDICATE DEVICE(S)

- Avinger Wildcat Catheter (K111338)
- Safe-Cross® Radio Frequency Total Occlusion Crossing System ("Safe-Cross System") (K050916)

INDICATIONS FOR USE

The Ocelot System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation as an adjunct to fluoroscopy. The Ocelot System is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

DEVICE DESCRIPTION

The Ocelot System consists of the Ocelot Catheter, the Lightbox Console and the Umbilical. The Ocelot Catheter is an over-the-wire device that is compatible with a 6F sheath and 0.014" guidewire. The Ocelot Catheter has a working length of 110cm and incorporates an optical fiber used to facilitate Optical Coherence Tomography (OCT)-assisted orientation as an adjunct to fluoroscopy.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Ocelot System. The Ocelot Cather operates using the same technological characteristics for the same intended use as its predicate in the Avinger family of catheters, the Wildcat Catheter. The Ocelot System provides information on intravascular orientation using a similar interferometry-based technology for the same intended use as the Safe-Cross System. The nonclinical and clinical testing results demonstrate that any differences in the technological characteristics between the subject and predicate devices do not raise any new issues of safety or effectiveness. Thus, the Ocelot System is substantially equivalent to the predicate devices.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Ocelot System to support a determination of substantial equivalence to the predicate devices. The non-clinical bench testing included:

- Design verification and bench validation studies
- Biocompatibility
- Sterilization
- Packaging and shelf-life
- Software verification and validation
- Electrical safety, electromagnetic compatibility, and laser safety testing

Two acute *in-vivo* animal studies were also conducted for the Ocelot System. One study evaluated the trackability of the catheter in the peripheral vasculature and one characterized the flow rate and the related pressures to capture OCT images. These studies were conducted in a healthy porcine model and supported the clinical use of the Ocelot System. The collective results of the non-clinical testing demonstrate that the Ocelot

System meets the established specifications necessary for consistent performance for its intended use.

CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

A multi-center, prospective, non-randomized study (CONNECT II Study) was conducted to evaluate the safety and effectiveness of the Ocelot System used to cross chronic total occlusions in the superficial femoral and popliteal arteries. Subjects were followed through 30-days post procedure.

The Ocelot System was used in 122 subjects enrolled in the study from 15 sites in the United States and European Union. The population consisted of those presenting with Peripheral Artery Disease who met all eligibility criteria, including documented Rutherford Classification ranging from 2-5 and angiographic evidence of 99-100% stenosed femoropopliteal arteries that were ≥ 1 cm and ≤ 30 cm in length. Primary safety and effectiveness endpoints were based on independent angiographic reviewers.

The primary safety endpoint was a composite endpoint identified by both site reported safety data (MAEs) and angiographic data (clinically significant perforations, embolizations and Grade C or greater dissections) assessed by independent angiographic reviewers. Two clinically significant perforation (2%) occurred at the time of the procedure, as identified by the independent angiographic reviewers. No further sequelae were reported by any of the subjects prior to discharge. There were no occurrences of MAEs (0.0%) or unanticipated adverse events. The primary safety endpoint was met.

The primary effectiveness endpoint, defined as successful CTO crossing by the Ocelot System and subsequent guidewire positioning through the distal true lumen (confirmed by angiography), was achieved in 97% of subjects. The primary effectiveness endpoint was met.

In conclusion, the results of the CONNECT II Study demonstrate that the Ocelot System was able to safely and effectively facilitate crossing of CTOs in the peripheral vasculature where a conventional guidewire was unsuccessful.

CONCLUSION

The results of the nonclinical and clinical testing demonstrate that the Ocelot System is a safe and effective device when used for the stated indication for use. The clinical testing demonstrates that the new technological characteristics employed by the Ocelot System do not raise any new issues of safety or effectiveness. Therefore, the Ocelot System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Avinger, Inc.
Mr. Albert Boniske
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Redwood City, CA 94063

SEP 18 2013

Re: K122380
Trade/Device Name: Ocelot System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: October 10, 2012
Received: October 11, 2012

Dear Mr. Boniske:

This letter corrects our substantially equivalent letter of November 7, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122380

Device Name: Ocelot System

Indications For Use:

The Ocelot System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation as an adjunct to fluoroscopy. The Ocelot System is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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